REMARKS

Introductory Comments:

Claims 3, 4, 7-10, 17 and 21-23 were examined in the Office Action under reply and variously rejected under (1) 35 U.S.C. §112 second paragraph (claims 3, 4 and 7-10); (2) 35 U.S.C. §102(b) (claims 17 and 21); and (3) 35 U.S.C. §103(a) (claim 17). Additionally, claim 17 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed as discussed more fully below.

Applicant notes with appreciation the allowance of claims 22 and 23, as well as the indication that claims 3, 4 and 7-10 are free of the art.

Overview of the Above Amendments:

The specification has been amended at page 6, to correct obvious typographical errors.

Claim 21 has been cancelled and claims 4, 7-9, 10 and 17 have been amended to recite the subject invention with greater particularity. Specifically, claims 4 and 10 now recite the recovery of the functionally equivalent fragment in the last step of the method. Claims 7-9 have been amended to delete reference to cancelled claim 2. Claim 17 has been amended to recite that the kit also includes a "labeled HCV E2 protein."

Support for the foregoing amendments can be found throughout the specification at, e.g., pages 7-8, bridging paragraph; page 8, lines 26-27 and page 31, lines 35-36.

Cancellation of claim 21 and amendment of claims 4, 7-9 and 10 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or unamended claims.

Rejections Under 35 U.S.C. §112, Second Paragraph:

Claims 3, 4 and 7-10 were rejected under 35 U.S.C. §112, second paragraph as indefinite. The Office notes the preamble of claim 4 recites a method for preparation of a protein "or for the preparation of a functionally equivalent fragment thereof" but the final step in the claim does not recite that a functionally equivalent fragment is prepared. Similarly, the Office argues that claim 10 does not include a final step that results in the preparation of the protein or the fragment. Applicant has amended claim 4 to recite the functionally equivalent fragment in the final step. Additionally, claim 10 has been amended to recite the recovery of the protein or the fragment in the final step. Thus, these bases for rejection have been overcome.

Claims 7-9 were rejected as indefinite as depending from cancelled claim 2. Claims 7-9 have been amended to delete the reference to claim 2. Thus, this basis for rejection has also been overcome and withdrawal thereof is respectfully requested.

Rejections Over the Art:

Claims 17 and 21 were rejected under 35 U.S.C. §102(b) as anticipated by Levy et al. (1991) *J. Biol. Chem.* 266:14597-14602 ("Levy") taken in light of Levy et al. (1998) *Annu. Rev. Immunol.* 16:89-109 ("Levy-2") and Pileri et al. (1998) *Science* 282:938-941 ("Pileri"). Claim 21 has been cancelled. With respect to claim 17 the Office argues that TAPA-1 described in Levy is CD81 and that the kit recited in claim 17 "is interpreted as no different from a composition comprising a protein having a molecular weight of about 24kd that specifically binds HCV E2...since 'diagnostic' represents intended use and does not impart any structural difference to the composition as recited in claim 17." Office Action, page 5. However, applicant submits that Levy fails to anticipate the claimed invention.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the

claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

Levy does not describe a kit as claimed and therefore cannot anticipate the present claims. In particular, Levy does not teach the presence of a labeled HCV E2 protein in a diagnostic kit. Accordingly, Levy does not anticipate claim 17 and this basis for rejection should be withdrawn.

Claim 17 was also rejected under 35 U.S.C. §103(a) as unpatentable over Levy, interpreted in light of Levy-2 and Pileri. The Office argues:

> A kit comprising TAPA-1, which is the same as Applicant's protein having a molecular weight of about 24kd, as evidenced by Levy et al. 1998 and Pileri et al., would have been obvious over Levy et al. 1991 because Levy et al. establish interest in and uses for the TAPA-1 protein, and because packaging reagents in the form of a kit is conventionally done for reasons of convenience and economy.

Office Action, page 6. However, applicant submits that Levy does not render claim 17 obvious.

It is well settled that *prima facie* obviousness can only be established if the following three basic criteria are met: (1) there must be some suggestion or motivation to modify the reference; (2) there must be a reasonable expectation of success (for the modification and/or combination); and (3) the prior art reference(s) must teach or suggest all the claim limitations. MPEP §2143. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *In re Vaeck,* 20 USPQ2d 1438 (Fed. Cir. 1991). The Office has not satisfied these criteria.

In particular, as explained above, Levy does not teach or suggest the presence of a labeled HCV E2 protein in a diagnostic kit. In fact, Levy did not understand the significance or function of his TAPA-1 protein. The last paragraph of Levy states: "The functions of the TAPA-1 related family of proteins are currently unknown." Thus, Levy fails to provide a motivation to include the claimed protein in a diagnostic kit and there is absolutely no suggestion to do so in combination with a labeled HCV protein since Levy was unaware that TAPA-1 bound to the E2 protein of HCV. The fact that Levy's protein may have the "inherent property" of binding HCV E2 is of no import. It is axiomatic that a retrospective view of inherency is not a substitute for

some teaching or suggestion to arrive at the claimed invention. That which may be inherent is not necessarily known, and obviousness cannot be predicated on the unknown. See, e.g., *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989).

Applicant submits, therefore, that the rejection under 35 U.S.C. §103 should also be withdrawn.

The Obviousness-type Double Patenting Rejection:

Claim 17 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 22 and 24-29 of USSN 09/755,251. Applicant will consider the propriety of filing a Terminal Disclaimer if claim 17 is considered allowable.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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Respectfully submitted,

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